



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

JUN 1 2011

Re: Invega Sustenna  
Docket No.: FDA-2009-E-0541

The Honorable David Kappos  
Under Secretary of Commerce for Intellectual Property  
Director of the United States Patent and Trademark Office  
Mail Stop Hatch-Waxman PTE  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Director Kappos:

This letter is in regard to the application for patent term extension for U.S. Patent No. 5,254,556, filed by Janssen, L.P. under 35 U.S.C. § 156. The human drug product claimed by the patent is Invega Sustenna (paliperidone palmitate), which was assigned new drug application (NDA) No. 22-264.

Invega Sustenna was approved on July 31, 2009. A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period under section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4).

Our records also indicate that Invega Sustenna represents the first permitted commercial marketing or use of the drug product, as required by 35 U.S.C. § 156(a)(5)(A). As noted in the November 8, 2010, letter from your Office of Patent Legal Administration, the Federal Circuit recently decided that the approval of an ester of a previously approved human drug product met the requirement in section 156(a)(5)(A) that the permission for the commercial marketing or use of the product claimed in the patent must be the first permitted commercial marketing or use.<sup>1</sup> The active ingredient in Invega Sustenna (paliperidone palmitate) is an ester of an active ingredient (paliperidone) that FDA has previously approved for commercial marketing or use in Invega tablets (approved December 19, 2006). However, FDA has not previously approved paliperidone palmitate itself, or an ester or salt of paliperidone palmitate, for commercial marketing. Therefore, in accordance with the analysis of the Federal Circuit's decision in *Photocure*<sup>2</sup> set forth in the Patent and Trademark Office's letter of November 4, 2010, for the purposes of patent term extension, Invega Sustenna is the first permitted commercial marketing or use of the "product," as defined under section 156(f)(1)-(2).

We have reviewed the dates contained in the application and have determined the regulatory review period for Invega Sustenna, the human drug product claimed by the patent. The total length of the regulatory review period for Invega Sustenna is 2,253 days. Of this time, 1,608

<sup>1</sup> *Photocure ASA v. Kappos*, 603 F.3d 1372 (Fed. Cir. 2010)

<sup>2</sup> *Id.*

days occurred during the testing phase and 645 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: June 2, 2003.

FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 2, 2003.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: October 26, 2007.

FDA has verified the applicant's claim that the new drug application (NDA) for Invega Sustenna (NDA 22-264) was submitted on October 26, 2007.

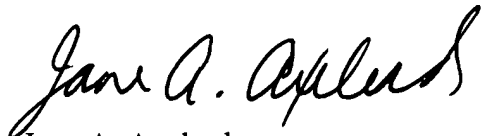
3. The date the application was approved: July 31, 2009.

FDA has verified the applicant's claim that NDA 22-264 was approved on July 31, 2009.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,



Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

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